

**In the Matter of
Oxyfresh Worldwide, Inc.**

ASSURANCE OF VOLUNTARY COMPLIANCE

This Assurance of Voluntary Compliance ("Assurance") is entered into among the Attorneys General of the States of Arkansas, Arizona, California, Connecticut, Florida, Massachusetts, New Mexico, Tennessee, Washington, and Wisconsin, along with the Commonwealths of Pennsylvania and Kentucky, by their respective Attorneys General ("Attorneys General"), and Oxyfresh Worldwide, Inc., its officers, directors, employees, agents, successors, and assigns ("Respondent"). The Attorneys General contend that Respondent has engaged in conduct in violation of their respective consumer protection statutes and/or food and drug laws, as more specifically described in Section III of this Assurance.

I. Definitions

1. As used in this Assurance, the following terms shall have the following meanings:

A. "Advertising" means any oral, written, graphic or pictorial statement or representation directed to consumers in the course of business, regardless of the medium of communication employed, and includes product packages, labels or product inserts.

B. "Labeling" means all labels and other written, printed, or graphic matter upon any containers or wrappers or any other written promotional materials, such as sales brochures, leaflets, or other written, printed, or graphic matter, which accompanies a product.

C. "Competent and reliable scientific evidence" means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, which have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

D. "Drug" means articles recognized in the official United States Pharmacopoeia, the official National Formulary, or any supplement to either of them, articles intended for use in the diagnosis, cure,

mitigation, treatment or prevention of disease in man or other animals, articles (other than food including dietary supplements) intended to affect the structure or any function of the body of man or other animals, and articles intended for use as a component of any article specified in this definition.

E. "New drug" means any drug, the composition of which is such that such drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, or any drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or a material time under such conditions.

II. BACKGROUND

2. Respondent, Oxyfresh Worldwide, Inc., a Washington corporation, sells a variety of products through a multi-level sales organization. Since at least 1997, Oxyfresh Worldwide, Inc. promoted a purported health related product, specifically, The Easy Quit Smokers Support System. The Easy Quit Smokers Support System has been promoted by independent sales representatives throughout the continental United States. Oxyfresh Worldwide, Inc. maintains a distribution facility located at 12928 East Indiana Ave., Spokane, Washington 99216, at which orders for these and other products are taken and from which products are shipped to consumers and distributors. Subsequent to the time Respondent was first contacted by the Attorneys General, Respondent ceased distribution of the Easy Quit Smokers Support System.

3. The Easy Quit Smokers Support System was marketed as a smoking deterrent product and sold by Respondent on the basis of its claimed healthful properties. The smoking deterrent product became the subject of numerous unsubstantiated claims based upon testimonials and other promotional materials provided by Respondent to persons engaged in the sale of The Easy Quit Smokers Support System. Those claims which include the claims prohibited in paragraph 11, below, became a matter of concern to the Attorneys General since they included claims that The Easy Quit Smokers Support System could treat, cure or prevent nicotine addiction, claims which rendered The Easy Quit Smokers Support System a new drug.

III. ALLEGATIONS

4. Respondent, Oxyfresh Worldwide, Inc., misrepresented to its distributors and consumers that The Easy Quit Smokers Support System was endorsed by a non-profit organization known as Doctors for a Smoke Free World, said organization having the charitable purpose of educating the public, particularly young people as to the hazards of smoking. In actuality, Doctors for a Smoke Free World never existed as a non-profit organization and the concept was used strictly as a marketing tool.

5. The Attorneys General allege that Respondent made false and misleading representations to consumers in marketing its health care product. Those allegations include, but are not limited to, the following: representations which rendered the product an unapproved new drug under federal and state law; representations regarding health benefits which were unsubstantiated; representations which claimed results which were not typical of ordinary consumer experience; and representations that the Respondent was affiliated with nationally recognized non-profit entities, when, in fact, no such affiliation existed. The Attorneys General further allege that these acts violated the consumer protection statutes and/or food and drug laws referenced above.

IV. GENERAL TERMS OF ASSURANCE

6. This Assurance is for settlement purposes only and does not constitute an admission by Respondent that any of the advertising or labeling claims made for its products:

A. are false, misleading, or deceptive; or

B. are in violation of any of the state consumer protection or food and drug laws of any state, or of any other state or federal law, regulation, or order.

7. The parties agree that this Assurance of Voluntary Compliance does not constitute an approval by the Attorneys General of any of the Respondent's past or future marketing or advertising practices and the Respondent shall not make any representation to the contrary.

8. The parties agree that this Assurance of Voluntary Compliance does not affect the rights, if any, or the obligations, if any, that any consumer or individual or entity may have vis-a-vis the Respondent and no such customer of Respondent is or may become a third-party beneficiary under this Assurance. Nothing herein shall be construed to deprive any persons of any private right of action under any law.

9. Respondent has read and understands this Assurance and enters into it voluntarily, having been advised by its legal counsel of the meaning and effect of each provision of this Assurance, or having waived the right to consult legal counsel in this regard.

V. PROHIBITED PRACTICES

10. Respondent Oxyfresh and Mr. Richard Brooke are prohibited from engaging in the following acts:

A. Selling or offering for sale any smoking cessation product unless and until the product complies with all requirements established by the U.S. Food and Drug Administration regarding the marketing of such product.

- B. Selling or offering for sale any smoking cessation product which contains any ingredient prohibited or not approved by the U.S. Food & Drug Administration.
- C. Falsely representing or implying an affiliation with or approval by any entity or person.
- D. Falsely representing the amount of any donation to a charitable or non-profit cause or implying that such donation indicated approval of any product or business practice of Respondent.
- E. Falsely representing the effectiveness of any product including smoking cessation products.
- F. The making of any false or misleading statements or using any false or misleading statements in advertising mediums or labeling of any type in connection with the sale or marketing of any of the products sold or marketed by Oxyfresh.

VI. AFFIRMATIVE ACTS

- 11. Respondent Oxyfresh and Mr. Richard Brooke will direct all of the distributors of products sold or marketed by Oxyfresh not to make any false or misleading statements or use any false or misleading statements in advertising mediums of any type in connection with the sale or marketing of any of the products sold or marketed by Oxyfresh.

VII. PAYMENT MADE TO THE STATES

- 12. Respondent shall pay the total sum of \$65,000.00, to be divided equally among the states. The aforementioned money is to be paid in equal monthly installments of \$5,000.00 each, beginning on the 5th day of June and by the 5th day of each month thereafter until the entire amount is paid.
- 13. The payments are to be made in the form of Cashier's Checks or Money Orders made payable to the Arkansas Attorney General's Office. All Payments should be sent to:

Teresa Brown

Senior Assistant Attorney General

323 Center St. Suite 200

Little Rock, AR. 72201

14. All monies obtained pursuant to paragraph 12 are to be used at the discretion of the Attorney General receiving the funds for any purpose allowed by the law of their state, including but not limited to, attorneys fees, investigative costs, state litigation, consumer education, public protection, or state consumer aid funds.

VIII. STIPULATIONS

15. It is agreed by the parties that:

A. Nothing in this Assurance shall prohibit Respondent from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration ("FDA"), or under any new drug application approved by the FDA.

13. Nothing in this Assurance shall prohibit Respondent from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990.